

REMARKS

Claims 1-14 and 65-71 constitute the pending claims in the present application. Applicants cancel, without prejudice, claims 67-70 which were previously withdrawn from consideration as directed to a nonelected invention. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

1. Claims 65-70 have been withdrawn from consideration as directed to a nonelected invention or species. Applicants have canceled claims 67-70 which depended from a canceled base claim. Applicants note that claims 65 and 66 were previously rejoined with the elected invention of Group I. Applicants acknowledge, however, that claims 65 and 66 are directed to a nonelected species and will be considered only upon indication of allowable subject matter.

2. The Examiner alleges that the Information Disclosure Statement filed on September 7, 2004 fails to comply with 37 CFR 1.98(a)(2). Specifically, the Examiner alleges that copies of Pennisi et al. and Gordon et al. have not been received, and that the date of re-submission of these references will be the relevant submission date for purposes of all certification requirements under 37 CFR 1.97(e). Applicants respectfully disagree with the Examiner's assessment of the present situation, as well as the appropriate course of action for remedying any discrepancies between the Patent Office's files and Applicants' files.

As a first point, Applicants maintain that Pennisi et al. and Gordon et al. were supplied with the Information Disclosure Statement filed on September 7, 2004. These references were included on Applicants' form PTO 1449. Furthermore, Applicants' itemized postcard indicated that the cited references were included with the materials sent to the US Patent Office on September 7, 2004. These materials create a presumption that the references were submitted by Applicants and received by the Patent Office. If these materials do not create such a presumption, then they would cease to perform any useful administrative function for either the Patent Office or Applicants.

If, as the present Office Action suggests, Pennisi et al. and Gordon et al. were somehow not received by the Patent Office, then such an alleged deficit should have been brought to Applicants' attention so that Applicants could fully address the discrepancy. By raising the issue

in the context of a Final Office Action, Applicants are given no real opportunity to respond to the alleged discrepancy without significant penalty. Placing this significant additional burden on Applicants undermines the entire evidentiary function of the itemized postcard.

Applicants further disagree with the Examiner's assessment that, for purposes of the certification requirements under 37 CFR 1.97(e), the date of re-submission should be the relevant submission date for these references. As detailed above, Applicants maintain that copies of Pennisi et al. and Gordon et al. have already been submitted. Even if the Patent Office contends that copies of Pennisi et al. and Gordon et al. were not received, that does not logically lead to the conclusion posited in the Final Office Action.

As a second point, Applicants note that regardless of whether copies of Pennisi et al. and Gordon et al. were received by the Patent Office with Applicants' submission filed September 7, 2004, Applicants have already fully complied with the minimum requirements for an Information Disclosure Statement, in accordance with 37 CFR 1.98. Specifically, Pennisi et al. and Gordon et al. were previously cited to the Patent Office during prosecution of a prior application (application serial no. 09/544,627) to which the present application claims priority. In accordance with MPEP 609, "[t]he examiner will consider information which has been considered by the Office in a parent application." MPEP 609. Thus, regardless of whether Applicants elect to submit copies of these references, Applicants are in compliance with the minimum requirements for an Information Disclosure Statement.

To expedite review of the cited art and allowance of the present application, Applicants enclose herewith copies of Pennisi et al. and Gordon et al. Applicants' submission of courtesy copies of these previously submitted references does not alter the relevant submission date of the references for purposes of the certification requirements under 37 CFR 1.97(e). Applicants have, however, enclosed a new form PTO 1449 to provide an appropriate place for the Examiner to indicate review of these reference and to ensure that these references are listed on a patent issuing from this application.

3. The specification is objected to for containing an embedded hyperlink. Applicants' amendment to the specification is believed to obviate this objection.

MPEP 608.01 instructs the Examiner to “... review patent applications to make certain that hyperlinks and other forms of browser-executable code, especially commercial site URLs, are not included in a patent application. Examples of a hyperlink or a browser-executable code are a URL placed between these symbols “< >” and http:// followed by a URL address.” MPEP 608.01. In accordance with the guidance provided by MPEP 608.01, Applicants have amended the specification to delete the following: http://. Reconsideration and withdrawal of this objection are requested.

4. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, for allegedly failing to comply with the written description requirement. Specifically, claim 7 allegedly contains new matter. Applicants traverse this rejection and contend that the rejection is moot in light of the amended claim.

Applicants contend that the specification provides explicit support for recitation of informative genes that correlate with genes encoding expression products. As referenced in Applicants’ previous response, page 21, lines 1-13 of the specification indicates Applicants’ appreciation that the term “expression products” includes both protein and nucleic acid products. However, the specification is not limited to this generalized reference to expression products. Applicants contend that page 46, line 21-page 47, line 28 and figure 3B provide explicit support for claim 7.

Applicants further note that compliance with 35 U.S.C. 112, first paragraph, does not require *in haec verba* support for the claimed subject matter. MPEP 2163. All that is required is that claim limitations “be supported in the specification through express, implicit, or inherent disclosure.” Applicants contend that this standard is amply satisfied.

Nevertheless, to expedite prosecution, Applicants have amended the claims to delete explicit reference to “genes encoding expression products.” Applicants’ amendments are not in acquiescence to the rejection, nor do they narrow the scope of the claims. Reconsideration and withdrawal of the rejection are respectfully requested.

5. Claims 9-14 are rejected under 35 U.S.C. 112, second paragraph, as indefinite for allegedly failing to particularly point out and distinctly claim the subject matter that Applicants

regard as the invention. Applicants traverse this rejection and contend that the rejection is moot in light of the amended claims.

The Office Action states that claim 9 is rejected for lacking antecedent support for recitation of “the one or more classes” in line 6. Based on the amendment suggested by the Examiner, Applicants assume that the rejection is based on an alleged lack of support for recitation of “the one or more genes” in line 6, and Applicants have amended claim 9 to incorporate the Examiner’s suggestion. Applicants’ amendment is believed to obviate the rejection. If, however, Applicants are incorrect in the interpretation of this rejection, Applicants respectfully request clarification.

Claim 10 is rejected for allegedly lacking sufficient antecedent basis for recitation of “the first class” and “the second class” in the last two lines of the claim. Applicants traverse this rejection. Applicants direct the Examiner’s attention to line 6 of claim 10 where “a first class and a second class” is recited, thereby providing sufficient antecedent support for subsequent recitation of “the first class” and “the second class”. Accordingly, Applicants contend that claim 10 satisfies all of the requirements under 35 U.S.C. 112, second paragraph.

6. Claims 1-14 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zheng et al. in view of Eisen et al. and Tamayo et al. Applicants traverse this rejection.

As a first point, Applicants note that the rejection under 35 U.S.C. 103(a) is a new ground for rejection. Although the Office Action alleges that the new ground for rejection was necessitated by Applicants’ previous amendments, Applicants disagree with this assessment. Previous claim 1 was directed to a method of assigning a sample to a known or putative class, comprising determining a weighted vote for one or more informative genes in said sample in accordance with a model built with a weighted voting scheme, wherein the magnitude of each vote depends on the expression level of the gene in said sample and on the degree of correlation of the gene’s expression with class distinction; and summing the votes to determine a winning class and a prediction strength, wherein said sample is assigned to the winning class if the prediction strength is greater than a prediction strength threshold.

In Applicants' previous response, Applicants made a number of amendments to improve the clarity of the claims and to further satisfy the requirements of 35 U.S.C. 112, second paragraph. Additionally, Applicants amended the claims to more particularly point out that the claim is directed to a method of assigning a sample to a known class, rather than to a known or putative class. However, the claim remained virtually unchanged with regard to the steps used to assign the sample to the known class. Accordingly, if the present rejection under 35 U.S.C. 103(a) is relevant to the currently pending claims, it was relevant to the previously pending claims and could have been raised in the prior Office Action. Given that the rejection was not necessitated by Applicants' previous amendment, the present Office Action should not have been made final. MPEP 706.07(a). Reconsideration and withdrawal of the finality of the Office Action and entry of this amendment are respectfully requested.

Regardless of whether the present Office Action was rightfully made final, Applicants contend that the cited references (Zheng et al. in view of Eisen et al. and Tamayo et al.) fail to undermine the patentability of the claimed invention. Applicants disagree with the entire basis of the rejection, whereby three references were cobbled together and viewed with impermissible hindsight in light of the teachings of the present application.

Nevertheless, to expedite prosecution, Applicants enclose herewith the declaration of Todd R. Golub, Eric S. Lander, Jill Mesirov, Donna Slonim, and Pablo Tamayo pursuant to *In Re Katz*. Applicants detail below the relevance of this declaration to the present rejection. Applicants note for the record that submission of the declaration is not in acquiescence to the rejection under 35 U.S.C. 103(a).

Tamayo et al. was published in March 1999, less than one year before the effective filing date of the present application. Thus, Tamayo et al. initially appears to be available as prior art under 35 U.S.C. 102(a). In response, Applicants submit herewith copies of the declaration of Todd R. Golub, Eric S. Lander, Jill Mesirov, Donna Slonim, and Pablo Tamayo pursuant to *In Re Katz*. Applicants note that the declaration was previously submitted during prosecution of parent application serial number 09/544,627, and is specifically relevant to the availability of Tamayo et al as prior art.

The authors of Tamayo et al. include the five co-inventors of the present application, as well as three additional authors, Mr. Zhu, Mr. Kitareewan, and Mr. Dmitrovsky. The declaration is signed by the five co-inventors of the present application and states that the additional coauthors did not contribute to the conception of the claimed invention. In particular, the declaration states that Mr. Zhu, Mr. Kitareewan, and Mr. Dmitrovsky provided materials and/or performed experimental procedures according to standard laboratory protocols, and that Mr. Zhu, Mr. Kitareewan, and Mr. Dmitrovsky performed these experiments under the direction and supervision of one or more of the co-inventors. As such, Mr. Zhu, Mr. Kitareewan, and Mr. Dmitrovsky are not inventors of the invention presently claimed. The declaration states that Tamayo et al. is the inventors' own work. Accordingly, Tamayo et al. is not available as prior art against the present application because it is the inventors' own work and was published within one year of the effective filing date of the present application. MPEP 2132.01.

The remaining references, standing alone, do not teach or suggest the claimed invention. Accordingly, reconsideration and withdrawal of this rejected is requested.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000.

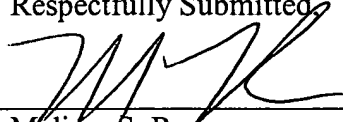
Please charge any deficiency or credit any overpayment in the fees that may be due in this matter to Deposit Account No. 18-1945, from which the undersigned is authorized to draw, under Order No. WIBL-P02-518.

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Respectfully Submitted,



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